510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number: #K040275

B. Analyte(s): APTT, PT, AT III, TT, FIB, Protein C/S, Plasminogen, D-dimer; Factors II, V, VII, VIII, IX, X, XI and XII.

C. Type of Test: N/A

D. Applicant: Bio-Rad Laboratories

E. Proprietary and Established Names: Lyphochek® Hemostasis Control, Levels 1, 2 and 3

F. Regulatory Information:

1. Regulation section: 21 CFR Section 864.5425 – Multipurpose System for in-vitro Coagulation Studies

2. Classification: Class II

3. Product Code: GGN – Coagulation Control Plasma

4. Panel: Hematology (81)

G. Intended Use:

1. Intended use(s):
   Lyphochek® Hemostasis Control is intended for use as an assayed quality control plasma to monitor the precision of laboratory testing procedures for analytes listed in the package insert. [See "**B. Analyte(s):"** above]

2. Indication(s) for use: Same as the Intended Use.

3. Special condition for use statement(s):

4. Special instrument Requirements: This quality control (QC) device has been assayed using methods/instruments by these companies: BioMerieux, Chromogenix, Dade Behring, Diagnostica Stago, Instrumentation Laboratories/Hemoliance and Roche.

H. Device Description: Lyphochek® Hemostasis Control, Levels 1, 2 and 3, is prepared from human plasma. Purified bio chemicals and preservatives are added; and the control is provided in a lyophilized form for increased stability. It is supplied in (12) x 1ml vials.

I. Substantial Equivalence Information:

1. Predicate device name(s): Bio-Rad Lyphochek® Hemostasis Control, Levels 1 and 2

2. Predicate K number(s):
#K020878

3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	Assayed hemostasis QC	Same
Matrix	Lyophilized human plasma	Same
Shelf-life	(3) years at 2º - 8º C.	Same
Reconstituted stability	(8) hours at 2º - 25º C.	Same
Differences		
Item	**Device**	**Predicate**
Assayed analytes	(17)	(16)
Levels	Tri-level	Bi-level
Additional analyte	D-dimer	None

J. Standard/Guidance Document Referenced (if applicable):

K. Test Principle: Various instrument/test methods under "Special Instrument Requirements" and listed on the assay sheet.

L. Performance Characteristics (if/when applicable): N/A

1. Analytical performance:
   a. *Precision/Reproducibility:*
   b. *Linearity/assay reportable range:*
   c. *Traceability (controls, calibrators, or method):*
   d. *Detection limit:*
   e. *Analytical specificity:*

f. Assay cut-off:

2. Comparison studies:
    a. Method comparison with predicate device:

    b. Matrix comparison:

3. Clinical studies:
    a. Clinical sensitivity:

    b. Clinical specificity:

    c. Other clinical supportive data (when a and b are not applicable):

4. Clinical cut-off:

5. Expected values/Reference range:

M. Conclusion:

The device is substantially equivalent to a legally marketed device.